Hartford HealthCare
Hartford Hospital

6816

# INFORMED CONSENT FOR LONG TERM VENTRICULAR ASSIST DEVICE EVALUATION

Patient Name: _____

## Introduction

Your heart is weak and unable to pump enough blood to meet the needs of your body. This may make you feel tired and lead to organ dysfunction, organ failure and/or death. Implanting a Ventricular Assist Device (VAD) can play an important role in addressing this situation, either as a means of keeping you alive until a new heart becomes available, known as Bridge to Transplant (BTT), or as a definitive option, known as Destination Therapy (DT). A VAD can also be used as a Bridge to Decision or a Bridge to Recovery.

Ventricular Assist Device (VAD) implantation is major surgery with significant risks and benefits. It is critical to understand the evaluation process, procedure, potential complications, and the significant lifestyle changes you can expect living with the device. This form documents that you were informed of the evaluation process and are willing to proceed with the VAD implant surgery.

**VAD as Long-Term Therapy:** Many patients with end-stage heart failure are candidates for heart transplantation. If you are waiting for a new heart and start to get sicker, or if a very long wait time is anticipated, a VAD can be implanted to keep you alive until a new heart becomes available. This is known as using a VAD as a Bridge to-Transplant. Others either choose not to have a heart transplant or are not a candidate for heart transplantation. Those patients can live on a VAD device as, "Destination Therapy."

**VAD as Short-Term Therapy:** Not all patients with severe heart failure are best served by a heart transplant, and may need time to become a transplant candidate or may recover. If you are such a patient a VAD, can be implanted. This use of a VAD is called Bridge to Decision or Bridge to Recovery. One can transition from Short-Term Therapy to Long-Term therapy without further intervention if clinically indicated allowing you to live for many years to come.

## The VAD

An VAD is a blood pump designed to help restore the flow of blood through the body. It assists your heart, but does not replace it. The HeartMate 3 is the durable VAD pump used at Hartford Hospital. This device is approved by the Food and Drug Administration (FDA) for both BTT and DT indications. The system has the following components:

- The heart pump
- A driveline (power cord) which passes through the skin
- An external power source
- A small computer (controller) that controls pump operation

After the VAD surgery, you and your caregiver(s) will be educated on managing the VAD device. You and your caregiver will need to be knowledgeable about the operation of the system and you will need to demonstrate that you can safely perform emergency procedures.

**The heart pump:** The VAD is designed to support the left ventricle, which is the main pumping chamber of the heart. The HeartMate 3 weighs a little less than half a pound. This pump is attached directly to the bottom of the left ventricle. It drains blood from the left ventricle and pumps blood into the aorta, the main artery that delivers blood to the rest of the body. You may hear a mechanical hum as the pump operates.

**The driveline:** The driveline is the "power cord" of the pump. It exits the skin on either the right or left side of your abdomen and it should be covered at all times by a sterile dressing. The driveline connects the pump inside your body to its external power source and the controller that keeps the pump running properly.

The exit site dressing on your abdomen needs to be changed using sterile technique. You and your caregiver(s) will be instructed on how to change the dressing before you are discharged home from the hospital or rehab facility.

**The external power source:** The HeartMate 3 pump is powered by batteries or by being connected directly to a unit that delivers power from a wall outlet to the pump. Two portable batteries that power the pump can be worn in either a special vest, shirt or shoulder bag, allowing considerable mobility. You will be instructed on how to switch power sources and how to charge the batteries. You will need to demonstrate your competency with these tasks before you are discharged home from the hospital or rehab facility.

**The controller:** The controller continuously monitors the pump and will provide audible and visual alarms in the event of a problem.

**VAD Evaluation Process:**
The VAD evaluation is a comprehensive work-up of your health and lifestyle to determine if the VAD may be a good option for you at this time. The evaluation can occur inpatient or outpatient. During the evaluation, you will meet with various team members to complete testing and consultations to gather all information needed. You will also meet with the VAD coordinator and receive an educational overview about the device. You will have the opportunity to ask questions, read additional materials, and meet a patient living with an VAD.

**VAD Implant Procedure**
The implant requires open heart surgery. You will meet with our cardiothoracic surgical team to review the surgery in detail.

**Possible risks of VAD**
- **Infection**
- **Bleeding**
- **Stroke**

**Potential Benefits**
The VAD helps your heart pump more blood to your body. The increase in blood flow gives you more energy, improving your quality of life and prolonging it as well.

Sometimes a VAD will lower pressures inside your lungs which otherwise could make you NOT a candidate for a heart transplant. A VAD may also improve kidney function. Sometimes patients who are not transplant candidates can become candidates after prolonged VAD support. Your physicians will monitor your progress after VAD insertion and will let you know if your candidacy for heart transplantation changes.

A discussion was held with me reviewing data regarding both national and center specific survival and quality of life benefit for left ventricular assist device implant.

**Lifestyle and Body Image Changes**
You and your caregiver will have a VAD pump model demonstration and have a basic understanding of the device components, including batteries, power unit, driveline, and controller. You will review ways to wear the controller and batteries. You will also learn about the driveline exit site (where the device exits the body on the abdomen) and how to perform a dressing change.

We strongly recommend a 24-hour caregiver or support person following discharge from the hospital for 2 weeks and a backup support plan.

Improved circulation of blood after VAD insertion should enable you to return to your daily life with few restrictions. With time, you should be comfortable with all aspects of living with a VAD. There are some activities that should be avoided because the VAD equipment is electrical and is outside the body. Examples of some restrictions include:

- No submersion in water (no tub baths, hot tubs/jacuzzis, or swimming)
- No contact sports
- No participation in impact activities that may cause trauma to the device or driveline
- No sleeping with electric blankets or pads
- No vacuuming as too much static electricity could cause electrical shock and damage the pump or cause the pump to stop.
- Discussion with your healthcare provider is recommended prior to becoming pregnant

**Discharge Home**

To support a safe discharge home, you and your caregiver will be knowledgeable on managing your VAD. Your home environment should be satisfactory to adequately support the VAD equipment. You should have consistent electricity and phone services. Some VAD equipment should only be plugged into a grounded, 3-pronged electrical outlet. A home safety assessment will be completed by the VAD Coordinator before surgery to ensure these requirements are met.

You will need to adhere to strict medical management after VAD implant, including:

- Lifetime follow-up appointments and testing to monitor organ function, medications and VAD function
- Lifetime sterile dressing changes of driveline exit site by you or your designated caregiver
- Lifetime care for the VAD and its components by preventing trauma, kinks or damage to the driveline and maintaining clean equipment

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**Financial**
The following financial matters will be evaluated and discussed:

- Ongoing cost of medications and dressing change supplies
- Potential for denial of additional health, disability or life insurance coverage
- Future health issues related to VAD implantation that may not be covered by current insurance
  Alternative financial resources that may be available

**Alternative Treatments**
If you decide you do NOT want a VAD, you can choose to be treated with other therapies that include conventional medications. Your heart failure cardiologist can discuss those options with you.

**Patient Acknowledgement**
I read and reviewed all of the above information. ***I understand that this is consent for the evaluation process and a separate surgical consent will be obtained for implant if I am deemed a candidate and I choose to proceed***.

The risks and benefits of the procedure and the lifestyle changes I should make to be successful with my VAD were reviewed and discussed.

I have had an opportunity to ask questions and received answers to all my questions about my condition, risks and benefits of the procedure(s), potential complications, alternative options, and lifestyle and body image changes.

This evaluation consent may be revocable by me at any time, except to the extent it has already been relied upon.

_____M. D. Signed: _____
(Patient or legally authorized representative)

Date:_____Time:_____ Date:_____Time:_____

Interpreter responsible for explaining procedures and special treatment:

_____(Interpreter)

Patient unable to sign prior to surgery [ ❒ ] because:

_____

_____M.D. Date:_____Time:_____